

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

DAVID O'NEILL

Plaintiff,

v.

ROCHE DIAGNOSTICS CORPORATION,

Defendant.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR FALSE PATENT MARKING

Plaintiff DAVID O'NEILL ("Plaintiff"), by its attorneys, hereby complains against Defendant ROCHE DIAGNOSTICS CORPORATION ("Defendant") as follows:

**I.
NATURE OF THE CASE**

1. This is a *qui tam* action on behalf of the public for false patent marking under 35 U.S.C. §292.

2. As set forth below, Defendant has violated 35 U.S.C. §292(a), by marking certain of its ACCU-CHEK® branded products with United States Patent Numbers 4,891,319 ("the '319 Patent"), 4,924,879 ("the '879 Patent") and 4,999,582 ("the '582 Patent") (collectively, "the Expired Patents"), even though the '319 Patent has been expired since May 7, 2007, the '879 Patent has been expired since October 7, 2008, and the '582 Patent has been expired since December 15, 2009. Defendant marks certain of its ACCU-CHEK® branded products with the Expired Patents with the intent to deceive the public and to gain a competitive advantage in the market.

3. Plaintiff seeks an award of monetary damages against Defendant pursuant to 35 U.S.C. §292(b) of up to \$500 for each offense, with one-half going to the use of the United States and the other half going to the person bringing the action.

II. **JURISDICTION AND VENUE**

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. Venue properly lies in the Northern District of Illinois pursuant to 28 U.S.C. §§ 1391(c), and 1395(a), because Defendant's falsely marked product(s) were and are offered for sale and sold in this District.

6. This Court has personal jurisdiction over Defendant because it has sold and continues to sell its falsely marked products, in Illinois and in this District and/or in the stream of commerce with knowledge that they would be sold in Illinois and in this District. Upon information and belief, such sales by Defendant are substantial, continuous, and systematic.

III. **THE PARTIES**

7. Plaintiff is a person residing in Clarendon Hills, Illinois, which falls within the Northern District of Illinois.

8. Defendant ROCHE DIAGNOSTICS CORPORATION is a Corporation established under the laws of the State of Indiana with its principal place of business at 9115 Hague Road, Indianapolis, Indiana 46250.

9. Upon information and belief, Defendant is the maker of ACCU-CHEK® products and a leading provider of blood sugar monitoring systems and insulin pumps for the self-care of people with diabetes. In particular, Defendant currently sells, for example, but not limited to: (1) ACCU-CHEK® Compact Plus Diabetes Monitoring Kit, which includes the ACCU-CHEK®

Compact Plus Blood Glucose Meter and the detachable ACCU-CHEK® Softclix Plus Lancing Device; (2) ACCU-CHEK® Softclix Plus Lancing Device; (3) ACCU-CHEK® Softclix Lancets; (4) ACCU-CHEK® Aviva Diabetes Monitoring Kit, which includes the ACCU-CHEK® Aviva Blood Glucose Meter and the adjustable ACCU-CHEK® Multiclix Lancing Device; (5) ACCU-CHEK® Multiclix Lancing Device Kit; (6) ACCU-CHEK® Multiclix Lancets; (7) ACCU-CHEK® Aviva Test Strips; and (8) ACCU-CHEK® Comfort Curve Test Strips.

10. The ACCU-CHEK® Compact Plus Diabetes Monitoring Kit is currently sold in packaging marked as shown below:



CAUTION

A restricted license limits the use of the ACCU-CHEK® Compact Plus system (meter, drum and test strips contained therein) and the ACCU-CHEK® Softclix Plus lancing device system (lancing device and lancets) in the United States. Carefully read the Owner's Booklet before use.

This product may be covered by one or more of the following U.S. Patents: 5,720,924; 5,893,800; 5,575,400; 5,738,244; 5,630,986; 5,632,410; 5,510,266; 5,810,190; 5,463,467; 6,707,554; 6,379,317; 6,475,436; 5,824,074; Re. 35,803; 0530,424; and 4,924,879.

ACCU-CHEK, ACCU-CHEK COMPACT, DIABETES ASSISTANT, and SOFTCLIX are trademarks of Roche.

Distributed in the U.S.A. by

Roche Diagnostics

9115 Hague Road

Indianapolis, IN 46256

www.accu-chek.com

Made in Ireland

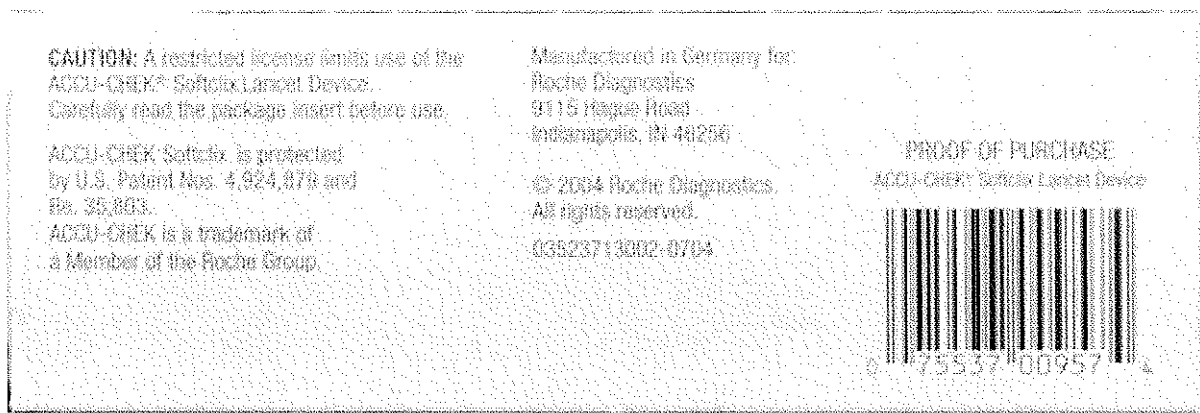
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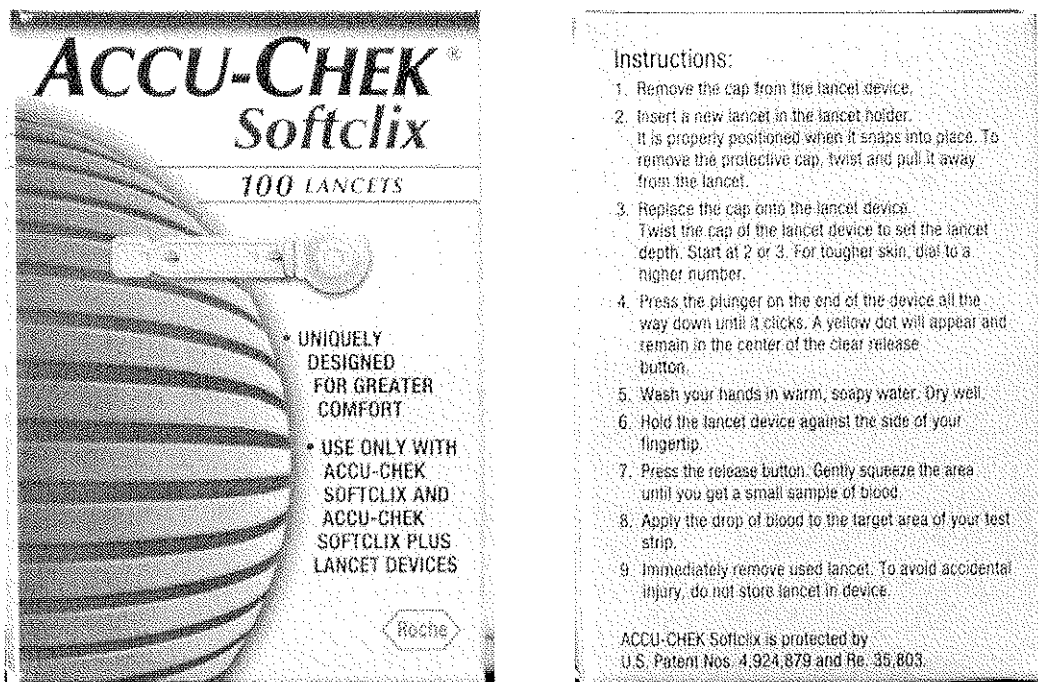
All rights reserved.

11. The ACCU-CHEK® Softclix Plus Lancing Device is currently sold in packaging marked as shown below:



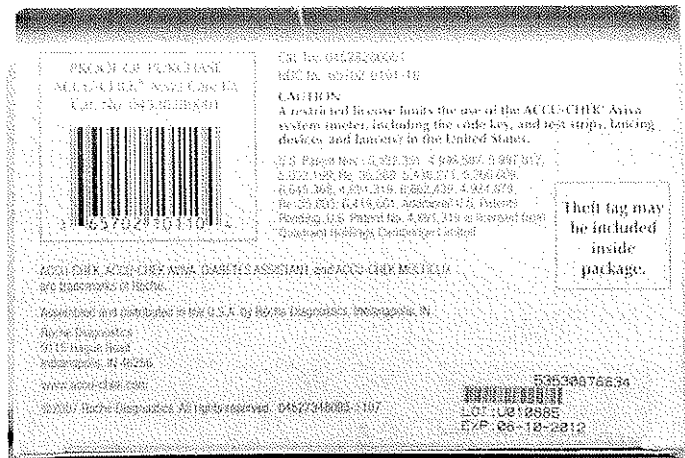
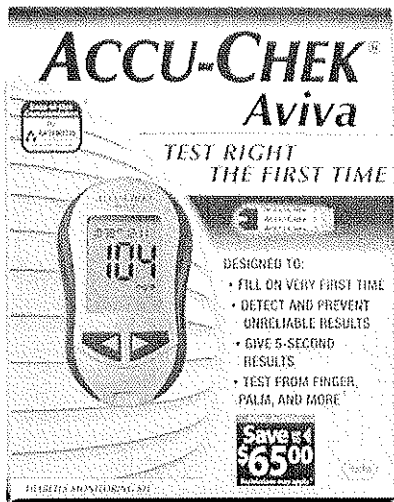


12. ACCU-CHEK® Softclix Lancets are currently sold in packaging marked as shown below:



ACCU-CHEK Softclix is protected by
U.S. Patent Nos. 4,924,879 and Re. 35,803.

13. The ACCU-CHEK® Aviva Diabetes Monitoring Kit is currently sold in packaging marked as shown below:



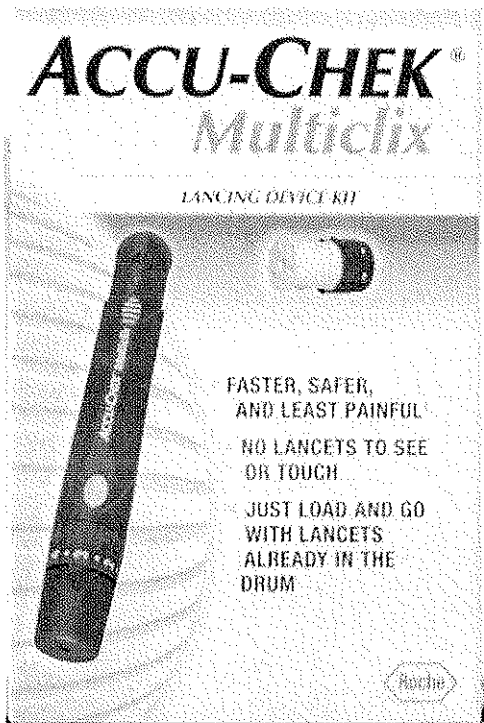
CAUTION

A restricted license limits the use of the ACCU-CHEK® Aviva system (meter, including the code key, and test strips, lancing devices and lancets) in the United States.

U.S. Patent Nos.: 5,352,351; 4,999,582; 5,997,817; 5,053,199; Re. 36,268; 5,438,271; 5,366,609; 6,645,368; 4,891,319; 6,662,439; 4,924,879; Re. 35,803; 6,419,661. Additional U.S. Patents Pending. U.S. Patent No. 4,891,319 is licensed from Quadrant Holdings Cambridge Limited.

Theft tag may
be included

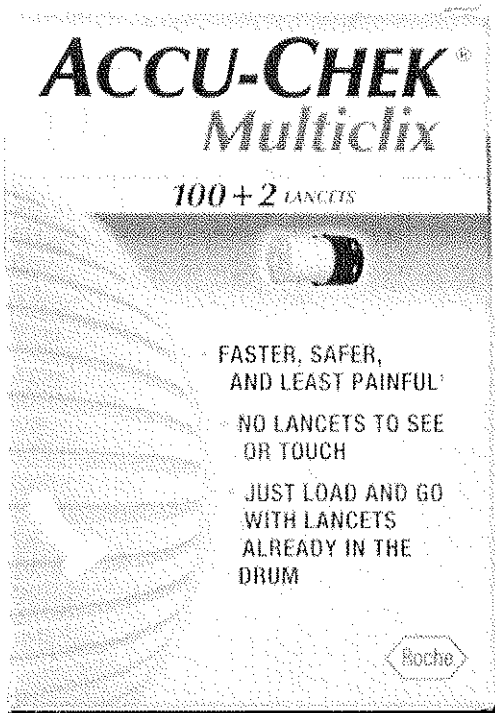
14. The ACCU-CHEK® Multiclix Lancing Device Kit is currently sold in packaging marked as shown below:



This product is protected by
U.S. Patent Nos. 4,924,879; 5,318,584;
Re35,803; 6,419,661.
Additional U.S. Patents pending.

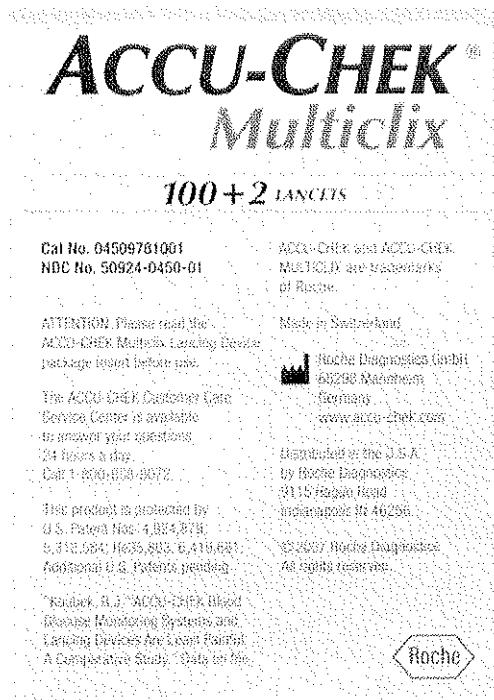
Distributed in the U.S.A.
by Roche Diagnostics
9115 Hague Road
Indianapolis IN 46256.

15. ACCU-CHEK® Multiclix Lancets are currently sold in packaging marked as shown below:



24 hours a day.
Call 1-800-858-8072.

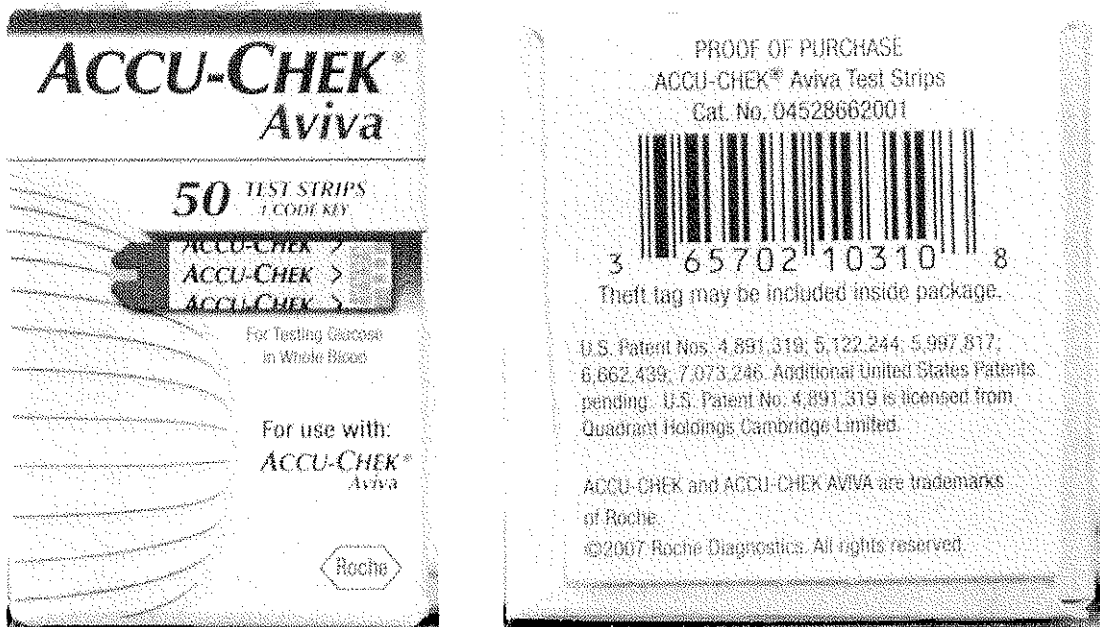
This product is protected by
U.S. Patent Nos. 4,924,879;
5,318,584; Re35,803; 6,419,661.
Additional U.S. Patents pending.



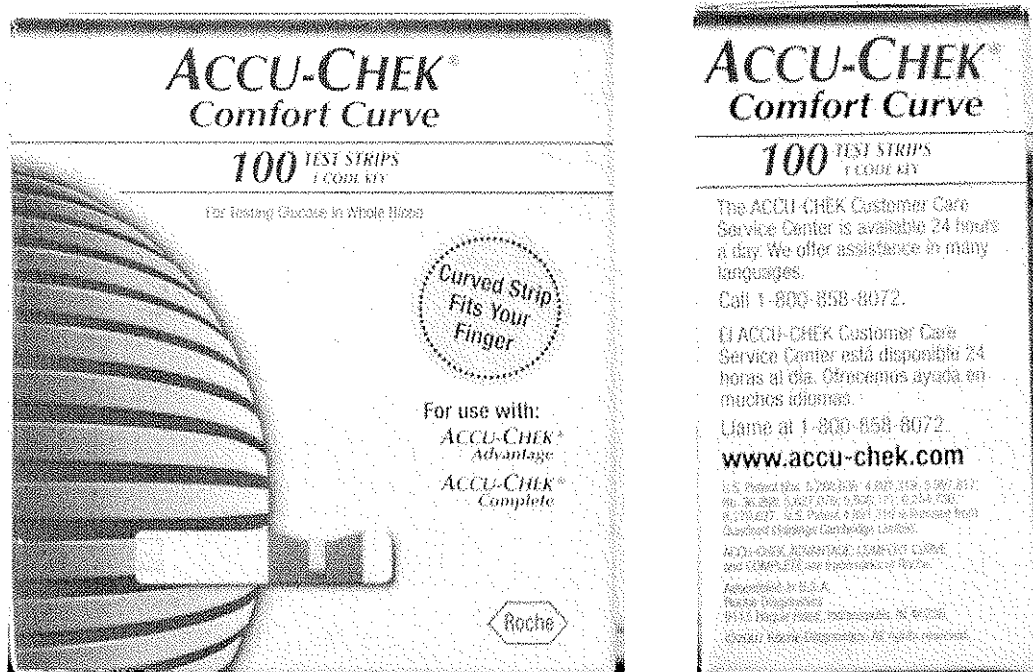
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by Roche Diagnostics
9115 Hague Road
Indianapolis IN 46256.

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16. ACCU-CHEK® Aviva Test Strips are currently sold in packaging marked as shown below:



17. ACCU-CHEK® Comfort Curve Test Strips are currently sold in packaging marked as shown below:



U.S. Patent Nos. 5,288,636; 4,891,319; 5,997,817;
Re. 36,268; 5,627,075; 5,508,171; 6,254,736;
6,270,637. U.S. Patent 4,891,319 is licensed from
Quadrant Holdings Cambridge Limited.

18. Defendant markets the ACCU-CHEK® Compact Plus Diabetes Monitoring Kit including the ACCU-CHEK® Softclix Plus Lancing Device as the “Least Painful Lancing Device” and “Unique lancet technology makes testing least painful.” (See for example, <https://www.accu-check.com/us/glucose-meters/compact-plus.html> last visited on Feb 20, 2010, as well as the product packaging)

19. Upon information and belief, Defendant is a subsidiary of F. Hoffmann–La Roche Ltd. is a Swiss global health-care company.

20. Upon information and belief, Defendant is a sophisticated company and has many decades of experience applying for, obtaining, and litigating patents.

21. Upon information and belief, Defendant has an in-house legal department.

22. Upon information and belief, attorneys in Defendant’s in-house legal department are responsible for Defendant’s intellectual property and marketing, labeling, and advertising law.

23. Upon information and belief, Defendant has previously accused companies of patent infringement and Defendant has been accused of patent infringement.

24. As a sophisticated company with, upon information and belief, in-house attorneys who regularly litigate or oversee litigation of patent infringement cases and who regularly prosecute or oversee patent prosecution, Defendant knows, or reasonably should know, of the requirements of 35 U.S.C. §292.

IV.

COUNT I - THE FALSE MARKING OF THE '319 PATENT

25. Plaintiff incorporates paragraphs 1-24 as if fully set forth herein.

26. When a patent expires, all monopoly rights in the patent terminate irrevocably. Therefore, a product marked with an expired patent is not currently protected by such expired patent.

27. Defendant by itself or by its representatives cannot genuinely believe that a patent does not expire and that patent rights apply even after its expiration.

28. The '319 Patent, entitled "Protection of Proteins and the Like," issued on January 2, 1990 and expired on May 7, 2007. A true and correct copy of the '319 Patent is attached hereto as Exhibit A.

29. Claim 1 of the '319 Patent states as follows:

"1. A method of protecting proteins or other biological macromolecules against denaturation during drying, comprising subjecting an aqueous system containing the protein or other biological macromolecule to drying at a temperature above freezing in the presence of trehalose in an amount between about 0.05 and 20 weight percent based on the total weight of said aqueous system."

30. Upon information and belief, Defendant has in the past marked, or caused to be marked, and presently marks, or causes to be marked, for example, but not limited to, at least the following products and/or packaging thereof, with the '319 Patent, with knowledge that the '319 Patent has expired: ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Aviva Test Strips, and ACCU-CHEK® Comfort Curve Test Strips.

31. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '319 Patent marked on the ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Aviva Test Strips, and ACCU-CHEK® Comfort Curve Test Strips has expired.

32. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Aviva Test Strips, and ACCU-CHEK® Comfort Curve Test Strips are not covered by the expired '319 Patent marked on such product because an expired patent has no monopoly rights.

33. Upon information and belief, Defendant intentionally included the expired '319 Patent in the patent markings of the ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Aviva Test Strips, and ACCU-CHEK® Comfort Curve Test Strips, in an attempt to prevent competitors from using the same or similar method of protecting proteins.

34. Upon information and belief, Defendant marks the ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Aviva Test Strips, and ACCU-CHEK® Comfort Curve Test Strips with the expired '319 Patent for the purpose of deceiving the public into believing that something contained in or embodied in the product is covered by or protected by the expired '319 patent.

35. Each false marking on the ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Aviva Test Strips, and ACCU-CHEK® Comfort Curve Test Strips is likely to, or at least has the potential to, discourage or deter persons and companies from commercializing competing products.

36. Defendant has wrongfully and illegally advertised a patent monopoly which it does not possess and, as a result, has benefitted commercially and financially by maintaining false statements of patent rights.

37. Upon information and belief, Defendant knows, or reasonably should know, that marking the ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Aviva Test Strips, and ACCU-CHEK® Comfort Curve Test Strips with false patent statements was and is illegal under Title 35 United States Code. At a minimum, Defendant had and has no reasonable

basis to believe that its use of the false markings was or is proper or otherwise permitted under federal law.

38. Upon information and belief, Defendant's marking of its ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Aviva Test Strips, and ACCU-CHEK® Comfort Curve Test Strips with the expired '319 Patent, as described above and/or as will be further later evidenced, has wrongfully quelled competition with respect to such products to an immeasurable extent thereby causing harm to the United States in an amount which cannot be readily determined.

39. Upon information and belief, for at least the reasons set forth herein, Defendant has wrongfully and illegally advertised a patent monopoly which it does not possess, and, as a result, has likely benefitted in at least maintaining its considerable market share with respect to the herein described ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Aviva Test Strips, and ACCU-CHEK® Comfort Curve Test Strips in the market place.

40. The instances of false marking alleged in Count I of this Complaint are representative and not meant to be exhaustive.

41. For at least the reasons provided herein, and/or for reasons which will be later evidenced, each expired patent which is marked on a product contributes to causing harm to the Plaintiff, the United States and the general public.

42. Thus, each expired patent marked on a product, directly or on the packaging thereof, multiplied by the number of products and/or packaging materials on which it appears is a separate "offense" pursuant to 35 U.S.C. §292(a).

IV.

COUNT II - THE FALSE MARKING OF THE '879 PATENT

43. Plaintiff incorporates paragraphs 1-42 as if fully set forth herein.

44. The '879 Patent, entitled "Blood Lancet Device," issued on May 15, 1990 and expired on October 7, 2008. A true and correct copy of the '879 Patent is attached hereto as Exhibit B.

45. The Abstract of the '879 Patent states in relevant parts as follows:

"A blood letting lancet assembly for puncturing the skin of the finger tip for home use that causes less pain includes a mechanism for reproducibly orienting the assembly on the finger tip. The blade may be moved to any of a plurality of indexed positions within the device. By indexing the blade to the next position and reproducibly orienting the device on the finger tip, the user can avoid a second puncture close to the first puncture which reduces pain. A new method for rapidly advancing and retracting the blade further reduces pain. An accessory capillary collects the exact volume of blood required for a test and avoids needless attempts to collect excessive blood." (Abstract)

46. Upon information and belief, Defendant has in the past marked, or caused to be marked, and presently marks, or causes to be marked, for example, but not limited to, at least the following products and/or packaging thereof, with the '879 Patent with knowledge that the '879 Patent has expired: ACCU-CHEK® Compact Plus Diabetes Monitoring Kit, ACCU-CHEK® Softclix Plus Lancing Device, ACCU-CHEK® Softclix Lancets, ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Multiclix Lancing Device Kit, and ACCU-CHEK® Multiclix Lancets.

47. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '879 Patent marked on the ACCU-CHEK® Compact Plus Diabetes Monitoring Kit, ACCU-CHEK® Softclix Plus Lancing Device, ACCU-CHEK® Softclix Lancets, ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Multiclix Lancing Device Kit, and ACCU-CHEK® Multiclix Lancets has expired.

48. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the ACCU-CHEK® Compact Plus Diabetes Monitoring Kit, ACCU-CHEK® Softclix Plus Lancing Device, ACCU-CHEK® Softclix Lancets, ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Multiclix Lancing Device Kit, and ACCU-CHEK® Multiclix Lancets are not covered by the expired '879 Patent marked on such product because an expired patent has no monopoly rights.

49. Upon information and belief, Defendant intentionally included the expired '879 Patent in the patent markings of the ACCU-CHEK® Compact Plus Diabetes Monitoring Kit, ACCU-CHEK® Softclix Plus Lancing Device, ACCU-CHEK® Softclix Lancets, ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Multiclix Lancing Device Kit, and ACCU-CHEK® Multiclix Lancets, in an attempt to prevent competitors from using the same or similar blood lancet assembly.

50. Upon information and belief, Defendant marks the ACCU-CHEK® Compact Plus Diabetes Monitoring Kit, ACCU-CHEK® Softclix Plus Lancing Device, ACCU-CHEK® Softclix Lancets, ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Multiclix Lancing Device Kit, and ACCU-CHEK® Multiclix Lancets with the expired '879 Patent for the purpose of deceiving the public into believing that something contained in or embodied in the product is covered by or protected by the expired '879 patent.

51. Each false marking on the ACCU-CHEK® Compact Plus Diabetes Monitoring Kit, ACCU-CHEK® Softclix Plus Lancing Device, ACCU-CHEK® Softclix Lancets, ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Multiclix Lancing Device Kit, and ACCU-CHEK® Multiclix Lancets is likely to, or at least has the potential to, discourage or deter persons and companies from commercializing competing products.

52. Defendant has wrongfully and illegally advertised a patent monopoly which it does not possess and, as a result, has benefitted commercially and financially by maintaining false statements of patent rights.

53. Upon information and belief, Defendant knows, or reasonably should know, that marking the ACCU-CHEK® Compact Plus Diabetes Monitoring Kit, ACCU-CHEK® Softclix Plus Lancing Device, ACCU-CHEK® Softclix Lancets, ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Multiclix Lancing Device Kit, and ACCU-CHEK® Multiclix Lancets with false patent statements was and is illegal under Title 35 United States Code. At a minimum, Defendant had and has no reasonable basis to believe that its use of the false markings was or is proper or otherwise permitted under federal law.

54. Upon information and belief, Defendant's marking of its ACCU-CHEK® Compact Plus Diabetes Monitoring Kit, ACCU-CHEK® Softclix Plus Lancing Device, ACCU-CHEK® Softclix Lancets, ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Multiclix Lancing Device Kit, and ACCU-CHEK® Multiclix Lancets with the expired '879 Patent, as described above and/or as will be further later evidenced, has wrongfully quelled competition with respect to such products to an immeasurable extent thereby causing harm to the United States in an amount which cannot be readily determined.

55. Upon information and belief, for at least the reasons set forth herein, Defendant has wrongfully and illegally advertised a patent monopoly which it does not possess, and, as a result, has likely benefitted in at least maintaining its considerable market share with respect to the herein described ACCU-CHEK® Compact Plus Diabetes Monitoring Kit, ACCU-CHEK® Softclix Plus Lancing Device, ACCU-CHEK® Softclix Lancets, ACCU-CHECK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Multiclix Lancing Device Kit, and ACCU-CHEK® Multiclix Lancets in the market place.

56. The instances of false marking alleged in Count II of this Complaint are representative and not meant to be exhaustive.

57. For at least the reasons provided herein, and/or for reasons which will be later evidenced, each expired patent which is marked on a product contributes to causing harm to the Plaintiff, the United States and the general public.

58. Thus, each expired patent marked on a product, directly or on the packaging thereof, multiplied by the number of products and/or packaging materials on which it appears is a separate "offense" pursuant to 35 U.S.C. §292(a).

V.
COUNT III - THE FALSE MARKING OF THE '582 PATENT

59. Plaintiff incorporates paragraphs 1-58 as if fully set forth herein.

60. The '582 Patent, entitled "Biosensor Electrode Excitation Circuit," issued on March 12, 1991 and expired on December 15, 2009. A true and correct copy of the '582 Patent is attached hereto as Exhibit C.

61. The Background Section of the '582 Patent states in relevant parts as follows:

"Accordingly, it is an object of this invention to provide a voltage excitation circuit for an amperometric biosensor which enables a potential applied to the biosensing cell to be accurately determined. It is a further object of this invention to provide a biosensing excitation circuit which provides a clear indication when a test cell is either improperly inserted or not inserted in the biosensing instrument." (col. 1, lines 57-64)

62. Upon information and belief, Defendant has in the past marked, or caused to be marked, and presently marks, or causes to be marked, for example, but not limited to, at least the following product and/or packaging thereof, with the '582 Patent: ACCU-CHECK® Aviva Diabetes Monitoring Kit.

63. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '582 Patent marked on the ACCU-CHECK® Aviva Diabetes Monitoring Kit has expired.

64. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the ACCU-CHECK® Aviva Diabetes Monitoring Kit is not covered by the expired '582 Patent marked on such product because an expired patent has no monopoly rights.

65. Upon information and belief, Defendant intentionally included the expired '582 Patent in the patent markings of the ACCU-CHECK® Aviva Diabetes Monitoring Kit, in an attempt to prevent competitors from using the same or similar blood lancet assembly.

66. Upon information and belief, Defendant marks the ACCU-CHECK® Aviva Diabetes Monitoring Kit with the expired '582 Patent for the purpose of deceiving the public into believing that something contained in or embodied in the product is covered by or protected by the expired '582 patent.

67. Each false marking on the ACCU-CHECK® Aviva Diabetes Monitoring Kit is likely to, or at least has the potential to, discourage or deter persons and companies from commercializing competing products.

68. Defendant has wrongfully and illegally advertised a patent monopoly which it does not possess and, as a result, has benefitted commercially and financially by maintaining false statements of patent rights.

69. Upon information and belief, Defendant knows, or reasonably should know, that marking the ACCU-CHECK® Aviva Diabetes Monitoring Kit with false patent statements was and is illegal under Title 35 United States Code. At a minimum, Defendant had and has no

reasonable basis to believe that its use of the false markings was or is proper or otherwise permitted under federal law.

70. Upon information and belief, Defendant's marking of its ACCU-CHECK® Aviva Diabetes Monitoring Kit with the expired '582 Patent, as described above and/or as will be further later evidenced, has wrongfully quelled competition with respect to such products to an immeasurable extent thereby causing harm to the United States in an amount which cannot be readily determined.

71. Upon information and belief, for at least the reasons set forth herein, Defendant has wrongfully and illegally advertised a patent monopoly which it does not possess, and, as a result, has likely benefitted in at least maintaining its considerable market share with respect to the herein described ACCU-CHECK® Aviva Diabetes Monitoring Kit in the market place.

72. The instances of false marking alleged in Count III of this Complaint are representative and not meant to be exhaustive.

73. For at least the reasons provided herein, and/or for reasons which will be later evidenced, each expired patent which is marked on a product contributes to causing harm to the Plaintiff, the United States and the general public.

74. Thus, each expired patent marked on a product, directly or on the packaging thereof, multiplied by the number of products and/or packaging materials on which it appears is a separate "offense" pursuant to 35 U.S.C. §292(a).

VI.
PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment against Defendant as follows:

- (a) A decree that Defendant has falsely marked products in violation of 35 U.S.C. §292;

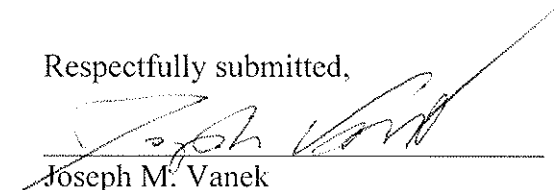
- (b) An award of monetary damages, pursuant to 35 U.S.C. § 292, in the form of a civil monetary fine of \$500 per false marking “offense,” or an alternative amount as determined by the Court, one half of which should be paid to the United States of America;
- (c) An accounting for any falsely marked products not presented at trial and an award by the Court of additional damages for any such falsely marked products;
- (d) Such other and further relief, at law or in equity, to which Plaintiff is justly entitled.

VI.
DEMAND FOR JURY TRIAL

Pursuant to Federal Rules of Civil Procedure Rule 38, Plaintiff hereby demands a jury trial on all issues triable by jury.

Dated: February 23, 2010

Respectfully submitted,



Joseph M. Vanek

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